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FOREIGN TITLE	(54A):	PROTHÈSE POUR PARTIES DU CORPS GLISSANT L'UNE PAR RAPPORT À L'AUTRE
ABSTRACT	(57):	

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It has long been known that serious traumas may cause permanent limitation of movement in an individual, resulting from the development of fibrous scar bonding or adhesions between bones, between adjacent muscles sliding over one another, or between tendons and tissues, and this bonding occurs most often during periods of immobilization in plaster casts. Such effects may occur, for instance, following a complicated or comminuted fracture or surgical procedure for installation of a prosthetic joint, or a synostosis of closely adjacent fractured bones may occur, such as, for example, the bony growth between the tibia and fibula following a fracture above the ankle.

The procedures for recovery and rehabilitation used to make these states less painful have, to date, not yielded very satisfactory results. Among such procedures, prosthetic tendon sheaths of silicon rubber may be manually placed for rehabilitation. A sheet or a similar and non-adherent analogous material has been used as an isolating membrane between the injured adjacent muscle bundles in clinical practice, but the results have not been very predictable or satisfactory, although the patient's state has sometimes been improved. The main flaw in these structures is the lack of stable positioning of the prosthesis, allowing it to form a ball and slide or slip and escape from the site of injury.

It is, therefore, desirable that this technique prevent or reduce such scar and restrictive bonding or adhesions between adjacent muscles sliding over one another as well as between bones, for example in the case of a synostosis or between bone and muscle where there should normally be a mutual sliding or analogous movement. The present invention permits the creation of an article designed to prevent or reduce such bonding or adhesion, with the device bicompatible **[sic]**, that is, inert relative to the bodily environment as well as bodily tissues or humors and secretions, and capable of being left permanently in place. The article of the present invention is flexible, supple and may be easily modified as desired and implanted by the surgeon. An important advantage of the prosthesis of the present invention is that it has been designed to self-position, thereby preventing displacement of the prosthesis outside the site of injury. A very significant advantage is that the manufacturing process of the present invention permits the production of membranes or prostheses which are preferably very thin, designed to function and favor naturally the functions of the affected parts. An advantage of the present invention is that it permits controlled penetration of the material receiving the tissues implanting in it through growth and guarantees that this characteristic of the material is adequately maintained. The above advantages, in addition to others, shall become evident during the following description.

The present invention concerns an article which prevents scar bonding or adhesion between the structures or elements comprising an animal body which normally slide over one another during various bodily movements. In particular, the invention concerns an article and procedure guaranteeing such mutual sliding between muscles, between bones and muscles and between bones after these elements have been damaged, for example following an operation, illness or trauma requiring immobilization of the site under consideration and which, as a result, often having this type of scar bonding or adhesion which causes movement to be restricted. The invention also concerns a procedure for preventing scar bonding or adhesion between the above-mentioned bodily structures through use of the device of the present invention.

The device under consideration is a thin flexible sheet comprised of two surfaces, one of which is a material with open pores, receiving the tissues which implant therein through growth, and the surface of the other is smooth and inert relative to the bodily humors or secretions or adjacent bodily structures. The material is such that it is compatible with the bodily humors and secretions, does not damage the bodily environment and is not attacked by the bodily humors or secretions, with this material made, for example, of polyethylene terephthalate sold under the "Dacron" brand name and made, for example, in the form of netting or velvet. In one variant, a cloth or material made of "Teflon" (polymerized tetrafluoroethylene)

or an analogous form may be used. In addition, the article may be made of one material such as polyurethane with one surface being smooth and non-porous while the opposite surface has open pores and can receive the tissues implanted through growth of these tissues. "Dacron" velvet is preferred because of the ease with which it can be combined with a biocompatible elastomer support or reinforcement and because of the fact that partial penetration, on only one side, of the velvet structure occurs leaving the opposite velvet surface with open pores not impregnated by the elastomer. Because of this fact, encouragement of implantation by growth of the osseous tissues or muscular tissues and receptivity to this implantation is not noticeably reduced. In other words, the article is in the form of a thin flexible biocompatible sheet comprising an elastomer support or reinforcement, the latter covered by a material with open pores receiving the tissue implanting itself through growth. The prosthesis or composite sheet may be between 0.25 mm and 1.25 mm thick.

As a support material, a biocompatible elastomer such as silicon rubber may be used. Such silicon rubber is sold under the brand name "Silastic" (produced by Dow Corning Corp.). This elastomer is compatible with humors and secretions of the body and of tissues and resists attack by the latter. Another advantage is that the surface of the velvet or the cloth with open pores is continuous on the surface of the elastomer but, if desired, it may be interrupted or discontinued. At least a part of the rubber is covered by a cloth with open pores sufficient to induce attachment to a bodily structure against which it is placed, with this cloth surface being preferably continuous on a part of the surface of the elastomer, leaving the edges or periphery free. Another advantage is that the elastomer support surface is reinforced by a fibrous embedded material, particularly with a "Dacron" or "Teflon" netting. The elastomer or support sheet is preferably between 0.13 mm and 1.02 mm thick and the velvet sheet is between 0.25 mm and 0.50 mm thick.

In accordance with the manufacturing procedure for the article of the present invention, a thin sheet of appropriate biocompatible tissue or material, preferably of "Dacron" velvet, between 0.25 mm and 0.50 mm thick is placed on and against a non-vulcanized biocompatible elastomer sheet which may or may not be reinforced, such as silicon rubber, between 0.13 mm and 1.02 mm thick, preferably between 0.25 mm and 1.02 mm. Pressure between 1.4 kg/cm^2 and 7 kg/cm^2 is applied to the sheets arranged in this way, for a period of between 30 seconds to 5 minutes at ambient temperature, for example a temperature between 21° and 29.5°. For less deep penetration of the silicon into the material, lower times and pressures should be used, whereas for greater, although still controlled penetration, higher times and pressures should be used.

The non-vulcanized sheet is then placed between retaining frames or molds with appropriate ventilation so as to maintain a desired form and smooth surface finish throughout the vulcanization and hardening, and it is then placed in a heated oven for vulcanization and hardening. The oven temperature should be between 149° C and 176.7° C, and the material should be heated until vulcanization and hardening are complete, usually for a period of between 5 and 60 minutes. The vulcanized and hardened sheet is then sized to the desired size and form in accordance with the desired use, rinsed in distilled water free of pyrogenous bodies, and then sterilized, dried and used or wrapped and stored in an appropriate fashion.

In another embodiment of the process of the present invention and in order to obtain a secure, predictable and desired depth of penetration of the elastomer in the material with open pores, the fabric nap is first previously covered with a hydrosoluble material such as carboxymethyl-cellulose or methylcellulose or ethylcellulose, which protects the fiber or nap from impregnation or coating by the elastomer. This is especially important in an article obtained by shaping, molding or forming in which considerable and significant contact pressure with the mold is required to form the prosthesis and to maintain the prosthesis in such form while it assumes its final state by hardening. Subject to the heat of vulcanization,

the viscosity of the crude elastomer momentarily decreases, and without this previous coating treatment, uncontrolled migration of this elastomer could occur. The hydrosoluble material is then eliminated by rinsing in water.

To use the present prosthesis, a flexible sheet is cut or shaped, including the surface and support described above, to the size deemed necessary by the surgeon and the cut sheet is placed so that the surface of the material is placed against a surface of one of the adjacent structures, which slide over one another, which must be treated and the smooth rubber support is placed against the second adjacent structure(s) so as to be maintained in a position permitting mutual sliding with the first of these structures. The sheet is then attached, with sutures for example, to the first structure to which it will join because of the implantation of tissues due to growth, and this attachment occurs in chosen areas, particularly the peripheral regions.

The prosthesis may be used to preserve the sliding movement between bones in a joint such as the shoulder joint and the joints between the bones of the lower arm and wrist bones. There are, to be sure, other areas where the present invention will also prove useful.

The present invention will now be described with reference to the attached drawing in which:

Figure 1 is a perspective view of a prosthesis in accordance with the present invention and presented in the form of a sheet;

Figure 2 is a schematic sectional view demonstrating installation of a prosthesis in accordance with the present invention in a plastic quadriceps prosthesis required due to insufficient movement of the knee following trauma to the thigh or femur;

Figure 3 is a schematic perspective view demonstrating the prosthesis in accordance with the present invention placed on the crural muscle in a fracture of the femur, with the underlying muscles, etc., not shown so as not to overload the drawing;

Figure 4 is a schematic frontal vertical view of fractured bones of the lower part of a human leg just above the ankle, with this view demonstrating a prosthesis in accordance with the present invention placed on the affected part of the tibia.

Detailed description of the invention

The present invention will now be illustrated with a description of the treatment of a situation resulting from a complicated or comminuted fracture of a femur and in which a prosthesis in accordance with the present invention is placed between the upper muscles of the leg which normally slide over one another, but often have fibrous scar bonding or adhesions between them in this type of injury. The result of such adhesions is, of course, varying degrees of (usually permanent) reduction in knee movement. This method of implementation of the invention for avoiding such adhesion shall be described with reference to Figures 1 and 2.

The prosthesis represented in Figure 1 is sheet 10 including surface 11 of "Dacron" velvet and an opposite surface 12 of silicon rubber which, as represented sectionally in Figure 2, comprises a support for the velvet fiber 13 and does not penetrate completely so that fiber 13 remains sufficiently thick to incite the living tissue to implant by growth and to accommodate this tissue. Figure 2 is a schematic sectional view demonstrating placement of prosthesis 10 between crural muscle 14 and the rest of the quadriceps mechanism, in other words the external vastus lateralis muscle 15 and internal vastus lateralis

muscle 16 with the right anterior closely linked muscle 18 of the thigh.

The typical patient for whom the prosthesis of Figures 1 and 2 is designed, has undergone a complicated or comminuted fracture halfway from the diaphysis of the femur with associated damage to the soft tissue. With healing of the soft tissue and the bone and after the necessary immobilization for this healing, movement of the knee is often reduced by several degrees and the patient is seriously handicapped as a result. Use of prosthesis 10 helps to correct this condition.

With a rectilinear lateral incision, the quadriceps mechanism may be freed from the scar adhesion present in these constitutive parts and the membrane described may be inserted. Prosthetic sheet 10 is cut to the exact size and shape required and is implanted with sutures, for example four temporary-hold sutures at edges 19 and 20, to maintain it in its position for the time required for the tissue to implant via growth so as to yield permanent attachment. In a variant of this invention, it is possible to use this same procedure during the principal operation or first operation on a clean break free of contamination, as a prophylactic measure.

Another typical example in which the prosthesis of the present invention is beneficial is prevention of union or osseous synostosis between adjacent bones whose relative movement must be maintained in order to preserve normal function. One area where such a synostosis may occur is the ankle, where an ordinary type of fracture occurring between the tibia and fibula, may cause union of these bones, partially preventing normal dorsal flexion of the foot (lifting the toe). While such a fracture is healing, union between the tibia and the fibula may occur, at the site of the fracture. The wrist and forearm are sites where a similar synostosis fracture may occur. The prosthesis of the present invention may be used advantageously in this case to prevent the osseous bridge from reforming once this bridge has been excised. The present invention has been successfully used in the treatment of painful arthritis of the wrist involving the radius in addition to the associated wrist intermedium and radial.

In another clinical test, the patient was suffering from a fracture of the tibia and fibula immediately above the ankle as represented in Figure 4. The fracture line 25 cut the tibia 26 and fibula 27 slightly above the talus and after healing, dorsal flexion of the foot was noted to be severely compromised by immobilization of tibia the 26 and fibula 27 and the development of an osseous union between these bones. An incision was made, the osseous union excised and the prosthesis 10 was custom-made as previously described so as to be adjusted to the area and was placed as shown, with the two edges of the prosthesis 10 being attached to the tibia by temporary sutures 29. Normal walking and function were reestablished.

In the case of another patient who suffered from a complicated fracture of the femur, flexion of the knee was noted to be limited to approximately 20° because of an intermuscular scar. The operation was performed to introduce the prosthesis 10 between the crural muscle 14, as shown in Figure 2, and the rest of the quadriceps mechanism, in other words the external vastus lateralis muscle 15 and the internal vastus lateralis muscle 16 with the closely linked right anterior muscle 18 of the thigh. As can be seen in Figure 2, surface 13, where the tissue has implanted by growth, is placed in contact with the crural muscle 14 and the elastomer surface 12 is oriented toward the rest of the quadriceps mechanism. After this placement of the prosthesis 10, the opening of the joint to approximately 85° was reestablished.

It is understood that the preceding description was given solely for the purpose of illustration and is non-limiting in nature, and that variants or modifications may be added without leaving the general framework of the present invention as defined in the claims attached hereinafter. All the materials used for the manufacture of the article of the present invention are biocompatible.

CLAIMS

1. Prosthesis characterized by the fact that it is comprised of a flexible sheet comprising a surface with open pores receiving the tissues implanting through growth and a elastomer support with a smooth surface, this prosthesis being designed for permanent attachment to bodily tissues due to implantation by growth of said tissues.

2. Prosthesis in accordance with claim 1, characterized by the fact that the above-mentioned surface is a polyethylene terephthalate velvet.

3. Prosthesis in accordance with claim 1, characterized by the fact that the support is of silicon.

4. Prosthesis in accordance with claim 1, characterized by the fact that the surface with open pores receiving the tissues implanting by growth and said support are of polyurethane.

5. Prosthesis in accordance with claim 1, characterized by the fact that the above-cited support is reinforced by netting of biocompatible material.

6. Prosthesis in accordance with claim 5, characterized by the fact that said netting is of polyethylene terephthalate or polymerized tetrafluoroethylene.

7. Prosthesis comprised of a flexible biocompatible sheet consisting of a surface in a sheet with open pores, receiving tissues implanting through growth, and an elastomer support with a smooth surface, characterized by the fact that it is used in a device used during surgery to maintain the mutual sliding between adjacent tissue structures and that it is between 0.25 mm and 1.25 mm thick.

8. Prosthesis in accordance with claim 7, characterized by the fact that it is designed to maintain the potential for mutual sliding between adjacent muscles.

9. Prosthesis in accordance with claim 7, characterized by the fact that it is designed to maintain the potential for mutual sliding between muscles and bones.

10. Prosthesis in accordance with claim 7, characterized by the fact that it is designed to maintain the potential for mutual sliding between adjacent bones.

11. Procedure for maintaining or permitting the capacity for sliding between adjacent animal bodily structures usually sliding over one another and whose capacity for mutual sliding is compromised, with this procedure being characterized by the fact that it consists of: (a) cutting a prosthesis to the desired size and shape in accordance with any one of the preceding claims and in which the above-mentioned material and elastomer are compatible with the action of bodily fluids or humors and tissues and resistant relative to these fluids or humors or tissues, (b) introducing said sheet cut so that the surface formed by the material is placed against a surface of a first bodily structure and that said elastomer support is placed against a surface of a second bodily structure following a layout which normally permits sliding relative to said first bodily structure, and (c) attaching said sheet to said first bodily structure at chosen sites.

12. Prosthesis in accordance with claim 11, characterized by the fact that the material with open pores cited above is of velvet from the group including polyethylene terephthalate and polymerized tetrafluoroethylene.

13. Procedure in accordance with claim 11, characterized by the fact that the material cited above is of

polyethylene terephthalate.

14. Procedure in accordance with claim 11, characterized by the fact that the elastomer cited above is made of silicon rubber.

15. Procedure in accordance with claim 11, characterized by the fact that said sheet is attached to selected peripheral regions after being placed there.

16. Procedure in accordance with claim 11, characterized by the fact that the sheet cited above is introduced in such a way that the surface formed by the material is placed against a surface of muscle and that the elastomer support is placed against the adjacent muscle surfaces.

17. Procedure in accordance with claim 11, characterized by the fact that the prosthesis is introduced so that the surface formed by the material is placed against a bone surface and that the elastomer support is placed against the adjacent muscle surfaces.

18. Procedure in accordance with claim 11, characterized by the fact that the prosthesis is introduced so that the surface formed by the material is placed against the surface of a bone and that the surface formed by the elastomer is placed against an adjacent bone surface.

19. Procedure to prepare a prosthesis in accordance with any one of claims 1 to 10 comprised of a biocompatible sheet and designed to be placed between adjacent structures in an animal body, with said structures being usually found in a mutual arrangement permitting sliding one relative to another, with the above-mentioned process being characterized by the fact that a thin sheet of a non-vulcanized elastomer is placed in surface contact with the back surface of a thin sheet of material consisting of a surface with open pores receiving tissues implanting through growth and on said back surface, said sheets thus arranged are subjected to pressure of approximately 1.4 kg/cm^2 to 7 kg/cm^2 at ambient temperature to form a composite sheet comprised of a surface with open pores receiving tissues implanting through growth and an opposite surface of smooth elastomer, and said composite sheet is then heated for vulcanization and hardening of the above-mentioned elastomer, and the tissue and above-mentioned elastomer are biocompatible.

20. Procedure in accordance with claim 19, characterized by the fact that the above-mentioned tissue is of polyethylene terephthalate velvet.

21. Procedure in accordance with claim 19, characterized by the fact that the above-cited elastomer is of silicon rubber.

22. Procedure in accordance with claim 19, characterized by the fact that temperature is between 21° and 29.5°.

23. Procedure in accordance with claim 19, characterized by the fact that heating is at a temperature of between approximately 149° C and 176.7 °C.

24. Procedure in accordance with claim 19, characterized by the fact that the above-mentioned heating is performed for between 5 and 60 minutes.

25. Procedure in accordance with claim 19, characterized by the fact that the composite sheet is prevented from being deformed during the above-mentioned heating.

26. Procedure in accordance with claim 19, characterized by the fact that the elastomer sheet is between 0.13 and 1.02 mm thick.